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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,794	02/13/2001	Michael K. Kwan	07078-003003	9975

22434 7590 11/18/2003

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/18/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,794

Applicant(s)

KWAN ET AL.

Examiner

Javier G. Blanco

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19, 20 and 24-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 20 and 24-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 19, 26, and 36 are objected to because of the following informalities:
 - a. Regarding claim 19, please add a comma (--,--) after “biodegradable” (see line 2). Also, it seems a comma (--,--) is needed after “water-insoluble binder” (see line 5). Otherwise, it will appear that the “water-insoluble binder” is “effective to promote bone growth at a desired site of bone repair”. Please add --said composition is-- (or similar claim language) before “effective to promote bone growth at a desired site of bone repair” (see line 5).
 - b. Regarding claim 26, please delete the double space between “a porous” (see line 1), the space in “b inder” (see line 3), and the space in “c ross-linking” (see line 3).
 - c. Regarding claim 36, please add a comma (--,--) after “mineral” (see line 3).Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 26-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 3738

Regarding claims 26 and 36, the specification does not disclose (i) that the water-soluble binder is rendered insoluble by cross-linking, and (ii) that the mineral is immobilized within said matrix by said binder. The Examiner was not able to find a description on how the water-soluble binder is rendered insoluble by cross-linking. Also, according to the specification (see page 7, lines 8-10), the calcium phosphate particles are already immobilized when included in the matrix. Applicant has failed to specifically point out the support in the original disclosure for each of the newly presented claim limitations (M.P.E.P. 714.02). Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem under 35 U.S.C. 112, first paragraph, is corrected.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 19, 20, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 19, the limitation “and a water-insoluble binder effective to promote bone growth at a desired site of bone repair” (see lines 4-5) renders the claim vague and indefinite as to the scope of the invention. Is the composition the one “effective to promote bone growth at a desired site of bone repair”, or is it referring to the “water-insoluble binder”?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 19, 20, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Silver et al. (US 5,532,217 A).

Silver et al. teach a matrix composition comprising mineralized collagen fibers (see Abstract; see column 2, lines 29-39) admixed with a binder (e.g., gelatin or propylene glycol; see column 2, lines 50-57) and growth factors (see column 2, lines 58-64). The matrix composition is intended for bone replacement therapy and to induce repair in bony defects (see Abstract; see entire document). Silver et al. do not specifically teach that the shape retention is maintainable without fragmentation upon implantation. However, Silver et al. form the matrix composition in a similar manner as does the Applicant and for the same intended purpose, therefore, the shape retention property would inherently be the same.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3738

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silver et al. (US 5,532,217 A) in view of Rhee et al. (US 5,264,214 A).

Silver et al. teach a matrix composition as claimed in claims 19, 20, and 24 except for teaching that the binder comprises collagen. However, Rhee et al. disclose a matrix composition (e.g., fibrillar cross-linked collagen-polyethylene glycol; see column 5, lines 3-21 and lines 61-68; column 7, lines 37-49) comprising a binder (e.g., collagen or gelatin; see column 7, lines 37-49; column 20, lines 34-43). It should be noted that Silver et al. disclose gelatin as an example of a binder (see 102(e) rejection above). Rhee et al. is evidence that collagen or gelatin are equally useful as binders when admixed with a matrix composition. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used collagen as a binder since, in view of Rhee et al., both binders work equally well as binders when admixed with a matrix composition.

Response to Arguments

10. Applicant's arguments with respect to claim 19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3738

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

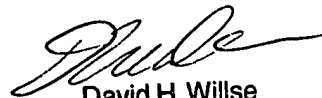
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



November 14, 2003



David H. Willse
Primary Examiner